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EXAMINER

ANGELL, JON E

ART UNIT PAPER NUMBER

1635

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/685,343

**Applicant(s)**

CHARNEAU ET AL.

**Examiner**

Jon Eric Angell

**Art Unit**

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 53-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/6/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Action is in response to the communication filed on 3/7/05. The amendment filed 3/7/05 is acknowledged. The amendment has been entered. Claims 53-80 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 4/6/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-55, 58-74, 76-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

Art Unit: 1635

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

MPEP §2163.06 notes:

*If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).*

MPEP §2163.02 teaches that:

*Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.*

MPEP §2163.06 further notes:

*When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).*

The instant claims are drawn to a isolated or purified nucleic acid having retroviral nucleic acid sequences including at least one cPPT sequence, at least one CTS sequence and the intervening pol sequences wherein any other sequence of pol is absent, as well as method of using the isolated nucleic acid to insert/express a heterologous nucleic acid sequence in a target cell, in vitro.

It is noted that in the response filed 3/7/2005, Applicants have indicated support for new claim 80 can be found on page 16, lines 15-17 of the specification (see page 10, first paragraph

Art Unit: 1635

of the response filed 3/7/2005). It is respectfully pointed out that Applicants have not indicated in the response where support for the amendment limiting the nucleic acid to having no other pol sequences other than at least one cPPT sequence at least one CTS sequence and the intervening pol sequences (e.g., see claims 53, 65, 71, 76, 78 and 79). The Examiner has thoroughly searched the specification for support for a nucleic acid that contains at least one cPPT sequence, at least one CTS sequence, the intervening pol sequences and no other pol sequence. It is noted that explicit support for the indicated nucleic acid sequence could not be found. However, the specification does disclose examples which describe steps for creating several nucleic acid vectors, including: TRIPΔU3 CMV GFP, TRIPΔU3 PL CMV GFP, TRIP EF1α GFP, and TRIPΔU3 EF1α GFP (see Example 1, pages 28-37 of the specification). The steps disclosed in Example 1 include the generation of a 178 base pair fragment pLAI3 (4793 to 4971) encompassing cPPT and CTS was amplified by PCR using the Nar TRIP+ (SEQ ID NO: 7) and Nar TRIP- (SEQ ID NO: 8) primers and inserted into a vector giving rise to the TRIP GFP plasmid vector having a CMV promoter (e.g., see p. 31, lines 9-20). For creation of the TRIP EF1α GFP and TRIPΔU3 EF1α GFP vectors, Example 1 indicates that the triplex triplex sequence and the EF1α promoter were first amplified separately with overlapping primers, and specifically indicates that the triplex sequence was amplified using the Nar TRIP+ and Mlu TRIP- (SEQ ID NO: 10) primers on the matrix pLai. The triplex sequence and the EF1α promoter sequence were then stuck together using a second round of PCR using the Nar TRIP+ and Bam EF1- primers. The triplex-EF1α sequence was then used to replace the CMV promoter in TRIP GFP and TRIPΔU3 GFP to create TRIP EF1α GFP and TRIPΔU3 EF1α GFP, respectively (e.g., see p. 31, line 21 through p. 32 line 19).

It is noted that the specification does not disclose or describe the sequence or features of pLAI3 or pLai which was used to create the triplex sequence that comprises the cPPT sequence, the CTS sequence and the intervening pol sequences without any other pol sequence. However, without a description of the sequence of pLAI3 and pLai it cannot be determined if the amplified fragment includes a cPPT sequence, a CTS sequence, intervening pol sequence and no other pol sequences. Furthermore, as indicated above, Example 1 discloses that a 178 base pair fragment of pLAI3 comprising the cPPT and CTS was amplified by PCR (p. 31, line 9). However, the specification also discloses, "Central strand displacement starts at the first nucleotide following the cPPT sequence... and stops in general 99 nucleotides downstream, at the ter2 site of the CTS sequence" (see p. 22, lines 2-5). Therefore, it does not appear that the 178 base pair fragment created using the Nar TRIP+ and Nar TRIP- primers and pLAI3 or the triplex sequence created using the Nar TRIP+ and Mlu TRIP- primers and pLai consist of the cPPT sequence, the CTS sequence, intervening pol sequence and no other pol sequences. As such, the specification does not appear to explicit or implicit support for the nucleic acid molecules encompassed by the instant claims.

Furthermore, the only explicit support found for any pol sequences other than the cPPT and CTS sequence is in Figure 1, which merely demonstrates that cPPT and CTS sequences are found within the pol gene. There does not appear to be any explicit support for a nucleic acid sequence having at least one cPPT sequence, at least one CTS sequence and the intervening pol sequences wherein any other sequence of pol is absent.

Should Applicants disagree, they are asked to identify by exact page and line number where explicit or implicit support for the claimed sequence can be found.

Art Unit: 1635

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, the instant claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53-80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,682,907 cited in the IDS filed by Applicants on April 6, 2005 (hereafter "the '907 patent").

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompassed by the claims of the '907 patent.

Specifically, the claims of the '907 patent are drawn to a nucleic acid sequence comprising cPPT

Art Unit: 1635

region and a CTS region. Since the '907 claims are drawn to nucleic acids "comprising: a cPPT and CTS sequences". It is noted that the cPPT region and CTS region are found within the retroviral pol gene. As such, the '907 claims encompass any nucleic acid vector comprising a retroviral pol gene.

The instant claims are specifically limited to a nucleic acid sequence having the cPPT site, the CTS site and the pol sequence that is between the cPPT and CTS sites, but does not include the entire retroviral pol sequence.

However, the specification of the '907 patent teaches a recombinant nucleic acid sequence comprising the limitations of the instant claims, including the cPPT and CTS regions and the intervening pol sequence without any other pol sequence (e.g., see Figures 2, 10, 11, 14, as well as column 14, lines 21-46), and teaches that this pol gene fragment is sufficient for triplex formation (e.g., see column 14, lines 21-46). Therefore, although the claims of the '907 patent are not identical to the instant claims they are not patentably distinct, as it would have been prima facie obvious to one of skill in the art at the time of filing that the '907 claims encompassed the instant claims based on the teaching of the specification of the '907 patent that the sequence comprising the cPPT and CTS regions could be a sequence comprising the cPPT, the CTS and the intervening sequence without any other pol sequence.

Additionally, claim 56 is drawn to the pTRIP $\Delta$ 3EF1 $\alpha$ GFP plasmid (deposited to CNCM as Accession number I-2328) wherein the plasmid appears to be similar to the claimed nucleic acid constructs disclosed in the '907 patent (e.g., see Figures 2, 10, 11 and 14) except that the CMV promoter element of the '907 patent has been replaced with the EF1 $\alpha$  promoter element in



Art Unit: 1635

the instant claim and that the U3 region of the retroviral vector has been removed in the instant claim.

It is noted that the '907 patent teaches that the promoter can be any promoter and specifically teaches, "An example of a promoter which can be used to control the expression of the transgene is the CMV promoter, the PGK promoter, or EF1 $\alpha$  promoter..." (See column 6, lines 31-35). The '907 patent also teaches that the U3 region of the retroviral vector can be removed. Specifically, column 7, lines 59-65 teaches, "A recombinant vector in accordance with a particular implementation of the invention can thus comprise all or a portion of the retroviral or retrotransposon LTR sequences... The LTR sequence can be partially deleted, in particular in the U3 region." Therefore, although the claims of the '907 patent are not identical to the instant claims they are not patentably distinct, as it would have been prima facie obvious to one of skill in the art at the time of filing that the '907 claims encompassed the instant claims based on the teaching of the specification of the '907 patent that the claimed nucleic acid sequence could comprise and EF1 $\alpha$  promoter and that the U3 region of the LTR could be deleted.

Furthermore, it appears that the nucleic comprising the EcoRI/BamHI fragment and ClaI fragment of pTRIP $\Delta$ 3EF1 $\alpha$ GFP plasmid (as in instant claim 75) would include any nucleic acid comprising the cPPT sequence, CTS sequence (as well as the intervening pol sequence) immediately followed by the EF1 $\alpha$  promoter. Therefore, although the nucleic acid sequences claimed in the '907 patent are not identical to the instant claimed plasmid, they are not patentably distinct as it would have been obvious, based on the teaching of the specification of

Art Unit: 1635

the '907 patent, that the EF1 $\alpha$  promoter could be used in place of the CMV promoter with a reasonable expectation of success, and the resulting nucleic acid would comprising the ClaI and EcoRI/BamHI fragment of pTRIP $\Delta$ 3EF1 $\alpha$ GFP.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 53-80 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,682,907 (hereafter "the '907 patent").

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37

Art Unit: 1635

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are specifically limited to a nucleic acid sequence having the cPPT site, the CTS site and the pol sequence that is between the cPPT and CTS sites, but does not include the entire retroviral pol sequence. Additionally, claim 56 is drawn to the pTRIPΔ3EF1αGFP plasmid (deposited to CNCM as Accession number I-2328), and claim 75 is drawn to a nucleic acid comprising the ClaI fragment and EcoRI/BamHI fragment of the pTRIPΔ3EF1αGFP plasmid.

The ‘907 patent teaches a recombinant nucleic acid sequence comprising the limitations of the instant claims, including the cPPT and CTS regions and the intervening pol sequence without any other pol sequence (e.g., see Figures 2, 10, 11, 14, as well as column 14, lines 21-46), and teaches that this pol gene fragment is sufficient for triplex formation (e.g., see column 14, lines 21-46). It is noted that the ‘907 patent teaches that the promoter can be any promoter and specifically teaches, “An example of a promoter which can be used to control the expression

Art Unit: 1635

of the transgene is the CMV promoter, the PGK promoter, or EF1 $\alpha$  promoter...” (See column 6, lines 31-35). The ‘907 patent also teaches that the U3 region of the retroviral vector can be removed. Specifically, column 7, lines 59-65 teaches, “A recombinant vector in accordance with a particular implementation of the invention can thus comprise all or a portion of the retroviral or retrotransposon LTR sequences... The LTR sequence can be partially deleted, in particular in the U3 region.”

Therefore, although the ‘907 patent does not appear to have reduced to practice the nucleic acid of the instant claims, it would have been prima facie obvious to one of skill in the art at the time of filing to modify the nucleic acid of the ‘907 claims such that the nucleic acid comprised a the cPPT, the CTS and the intervening sequence without any other pol sequence, as well as the EF1 $\alpha$  promoter instead of the CMV promoter, with a reasonable expectation of success. The motivation to make the changes are supplied by the ‘907 patent itself which teaches that the cPPT and CTS fragment of the pol gene is the critical element of the pol gene required for triplex formation, as well as the teaching that the EF1 $\alpha$  promoter is a desirable promoter to substitute for the CMV promoter, and that the U3 region of the retroviral vector can be deleted.

Furthermore, it appears that the nucleic comprising the EcoRI/BamHI fragment and ClaI fragment of pTRIP $\Delta$ 3EF1 $\alpha$ GFP plasmid (as in instant claim 75) would include any nucleic acid comprising the cPPT sequence, CTS sequence (as well as the intervening pol sequence) immediately followed by the EF1 $\alpha$  promoter. It noted that the claim nucleic acid described above, which is obvious in view of the teaching of the ‘907 patent, would necessarily comprise the ClaI and EcoRI/BamHI fragment of pTRIP $\Delta$ 3EF1 $\alpha$ GFP.

### ***Provisional Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53-80 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-28, 44-47 of copending Application No. 10/122,114 (hereafter "the '114 application"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are encompassed the claims of the '114 Application. The instant claims are specifically limited to a nucleic acid sequence having the cPPT site, the CTS site and the pol sequence that is between the cPPT and CTS sites, but does not include the entire retroviral pol sequence, as well as methods of using the nucleic acid to insert a heterologous nucleic acid of interest into a cell. Additionally, claim 56 is drawn to the pTRIPΔ3EF1αGFP plasmid (deposited to CNCM as Accession number I-2328), and claim 75 is drawn to a nucleic acid comprising the ClaI fragment and EcoRI/BamHI fragment of the pTRIPΔ3EF1αGFP plasmid.

The '114 application claims a process for inserting a nucleic acid of interest into the nucleus of a target cell, said method comprising exposing an isolated or purified nucleic acid

Art Unit: 1635

comprising at least one copy of the cPPT and CTS cis-acting regions of a retrovirus. It is noted that the '114 application does not explicitly claim using a nucleic acid comprising just the cPPT, CTS, and intervening pol sequence (i.e., without any other pol sequence), such as the pTRIPΔ3EF1αGFP plasmid. However, the '114 application discloses the production of the pTRIPΔ3EF1αGFP plasmid and the use of the pTRIPΔ3EF1αGFP plasmid for delivering a heterologous nucleic acid into a cell (e.g., see Figure 9 and Example 13 (pages 41-42)). Therefore, although the instant claims and the '114 claims are not identical they are not patentably distinct as it would have been obvious that the nucleic acid used to perform the method of the '114 claims could have been the pTRIPΔ3EF1αGFP plasmid, based on the teaching of the specification of the '114 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Specification*

The specification is objected to because it does not contain all of the information regarding the deposit of biological material pursuant to the regulations.

Specifically, 37 CFR 1.809(d) states:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
  - (1) The accession number for the deposit;
  - (2) The date of the deposit;

- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.

It is noted that the deposit information and declaration have been received by the Office (see papers received 4/30/02 and 6/16/03). It is also acknowledged that the claims now include reference to the deposit accession number (e.g., C.N.C.M. Accession Number I-2328 as in claim 56 and 75). However, the specification does not comprise all of the required information, such as the date of the deposit and the name and address of the depository, as required by 37 CFR 1.809(d).

It is noted that amending the specification to include all of the information required by 37 CFR 1.809(d) would obviate this objection.

### ***Response to Arguments***

Applicant's arguments filed 3/7/2005 have been fully considered. It is noted that the amendment to the claims limiting claims 53-55, 58-74, 76-80 to a nucleic acid having retroviral nucleic acid sequences including at least one cPPT sequence, at least one CTS sequence and the intervening pol sequences wherein any other sequence of pol is absent overcomes the rejections of claims under 35 USC 102(b). Furthermore, the amendment to claim 75 also overcomes the rejection of claim 75 under 35 USC 102(b).

The objection to claims 56 and 57 have been withdrawn in view of the amendment to the claims.

However, new grounds of rejection have been set forth for the reasons indicated above.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.  
Art Unit 1635

*Anne-Marie Falk*  
**ANNE-MARIE FALK, PH.D**  
**PRIMARY EXAMINER**